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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,211	12/05/2001	Milton D. Goldenberg	IMMU:003US1	5605
37013 7590 07/26/2007 ROSSI, KIMMS & McDOWELL LLP. P.O. BOX 826 ASHBURN, VA 20146-0826			EXAMINER CROWDER, CHUN	
			ART UNIT 1644	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/002,211

Applicant(s)

GOLDENBERG, MILTON D.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/24/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-86 and 93-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78-86 and 93-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 24, 2007, has been entered.

2. Applicant's amendment to the claims, filed on May 24, 2007, has been entered.

Claims 1-77 and 87-92 have been canceled.

Claims 78 and 93 have been amended.

Claims 94-101 have been added.

Claims 78-86 and 93-101 are pending and currently under consideration as they read on the originally elected species of immune thrombocytopenic purpura (ITP) and LL2 antibody.

3. This Office Action will be in response to applicant's arguments, filed on May 24, 2007.

The rejections of record can be found in the previous Office Actions.

4. Applicant's amendment to the Title, filed on May 24, 2007, has been entered.

5. In light of applicant's amendment to the claims, the previous rejections under 35 U.S.C. 112, second paragraph, 112, first paragraph, enablement, new matter, 35 U.S.C. 102 (b) and 102(e) have been withdrawn.

6. Applicant's assertion that the US Patent 7,074,403 and the instant application were commonly owned at the time the invention of this application was made is acknowledged.

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7. Given that applicant has timely filed terminal disclaimers in compliance with 37 C.F.R. 1.321, the previous nonstatutory double patenting rejections against US Patents 6,653,104 and 7,074,403 have been withdrawn.

8. Upon applicant's amendment to the claims filed on May 24, 2007, the following New Grounds of Rejections have been set forth herein.

9. This is a **New Ground of Rejection**. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 78-86 and 93-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 78-86 and 93-101 are indefinite in the recitation of "an immune disease in a subject" because the metes and bounds of the term is unclear and ambiguous.

The "immune disease" is not defined by the claims and the specification does not provide a standard for ascertaining the nature or parameters of the "an immune disease" that can encompass diseases with immune system being positively (e.g. autoimmune) or negatively (e.g. HIV) regulated; in turn, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the inventions or the nature or parameters by which to determine said metes and bounds.

It is suggested to amend the claims to recite the particular characteristics of the claimed "immune disease".

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B) Claim 93 is indefinite in the recitation of “an antibody having multiple epitope” because the metes and bounds of the phrase is unclear and ambiguous. The phrase is not defined by the claims, the specification does not provide a standard form ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

For examination purposes, the phrase is read as an antibody that binds multiple epitopes.

C) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 78-86, 93 and newly added claims 94-101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record.

The following *written description* rejection is set forth herein.

Claims 78-86, 93 and newly added claims 94-101 recite “B cell antibody or fragment thereof” as part of the invention.

Applicant’s arguments in conjunction with the references cited have been fully considered but have not been found persuasive.

Applicant argues that there were many antibodies recognizing B-cell antigens were publicly available at the time the claimed invention was made and one skill in the art would know how to make antibodies to B cell antigens; thus, applicant argues that one skill in the art would be able to practice the claimed method of treating an immune disorder using B-cell antibody.

This is not found persuasive for following reasons:

In contrast to applicant's assertion that one skill in the art would know how to practice the claimed method because B-cell antibodies were known and available at the time the invention was made, it is noted once again, the issue here is not whether one skill in the art can make the claimed B-cell antibodies, rather, the issue remains that the instant claims contain subject matter that was not described in the instant specification in such a way to reasonably convey to one skill in the art that the applicant had possession of the claimed invention at the time of filing the instant application.

The instant specification disclose only monoclonal LL2 antibody (e.g. see page 12 of the instant specification), therefore, applicant has disclosed only one species of the claimed "B-cell antibody". However, the instant claims encompass genus of "B-cell antibody or fragment thereof". The claimed antibody lacks a common structure essential for the function (e.g. antigen specificity) and the claims do not require any particular structure basis or testable functions be shared by the instant "B-cell antibody or fragment thereof".

For example, Seed et al. (EP 0739980) teach that a mammalian cell may contain up to 30,000 different mRNA sequences that can be translated to proteins (e.g. see page 3). Further as discussed in the previous Office Action mailed on August 17, 2006, Youinou et al. (Autoimmunity Reviews 2006 5:215-221, reference on PTO-892 mailed on August 17, 2006) B-cells express a variety of different cell surface markers depending on the B-cell subsets and locations (e.g. see Table 1 on page 217).

Therefore, the claimed genus of B-cell antibody, encompassing antibodies against any B-cell proteins in or on B-cells, is extremely large.

Applicant has not provided sufficient evidence that there is a known or disclosed correlation or the sufficiently detailed relevant identifying characteristics of the claimed "B-cell antibody or fragment thereof".

There is insufficient written description of the claimed antibody broadly encompassed by the claimed invention. There is a lack of disclosure of sufficient relevant identifying characteristics coupled with a known or disclosed correlation between function and structure of the broadly diverse antibodies (e.g. antigen specificity) employed in the claimed methods.

The claimed methods depend upon finding "B-cell antibody". Without such an antibody, the skilled artisan cannot practice the claimed method of treating an immune disease. It means little to invent a method if one does not have possession of the "B-cell antibody" that is essential to practice the method.

In conclusion, applicant has not provided sufficient identifying or distinguishing characteristics that support the written description of the genus of the "B-cell antibody or fragment thereof" broadly encompassed by the claimed method.

B) This is a **New Ground of Rejection**. Claim 93 recites "a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity".

The following *written description* rejection is set forth herein.

Claims 93 recites "a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity" as part of the invention.

There is insufficient written description in the specification as-filed of “a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity” as recited in the instant claims.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

The claims recite a genus “a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity” as part of the invention without providing a physical structure or testable functional activity for the antibody or fragment thereof.

The genus of the “a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity” are therefore extremely large. Applicant has disclosed a genus of antibody with dual or multiple antigen or epitope specificity without setting forth any species (e.g. actual epitopes or antigens). Thus Applicant has not disclosed any species of the “a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity”. The claimed “a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity” lack a common

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structure essential for their function and the claims do not require any particular structure basis or testable functions be shared by the instant antibody.

It does not appear that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus, especially with no disclosure of any of species.

“Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.” Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997).

The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406.

In the absence of disclosure of relevant, identifying characteristics of the “a B-cell antibody or fragment thereof wherein the antibody or fragment thereof is an antibody having multiple epitope or multiple specificity”, there is insufficient written disclosure under 35 U.S.C. 112, first paragraph.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

13. This is a New Ground of Rejection. Claims 78-86 and 93-101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although the claims are read on the elected species of immune thrombocytopenic purpura and LL2 antibody, the following is noted:

Claims 78-86 and 93-101 encompass a method of treating an immune disease by administering B-cell antibody or fragment thereof and/or B-cell antibody or fragment thereof that is conjugated to "therapeutic agent" and/or "a drug" and/or "a cytokine".

The specification as-filed does not enable one skilled in the art to practice the claimed invention without undue amount of experimentation.

The instant specification appears to disclose that antibody LL2 can be used to treat an immune disease such as immune thrombocytopenic purpura.

However, the specification as filed does not provide sufficient guidance, description, and working examples of the claimed method broadly encompassing any immune disease using any B-cell antibody. A person skilled in the art is not enabled to make and use the claimed methods of treating an immune disease using B-cell antibody or fragment thereof and/or B-cell antibody or fragment thereof that is conjugated to "therapeutic agent" and/or "a drug" and/or "a cytokine".

The specification provides for a plan or invitation for those skill in the art to experiment practicing the claimed invention but does not provide sufficient guidance or specificity as to how to execute the plan, but this is not adequate to constitute enablement in that the specification does not enable any person skilled in the art to make and use the invention as it reads on broad classes of immune diseases and B-cell antibodies.

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Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In addition, applicant admits that there are many B-cell antibodies. However, it is unpredictable whether all of the B-cell antibodies can be administered alone or conjugated to “therapeutic agent” and/or “a drug” and/or “a cytokine” to treat immune disease as broadly claimed.

For example, Vitetta et al. (Science 2006 313:308-309) teach that given the complex structure of antibodies, designing therapeutic antibodies can be unpredictable; in the case of anti-CD28 antibody, although preclinical data show that the antibody was safe when administered to two species of monkeys, healthy humans injected with the anti-CD28 antibody suffered immediate and profound side effects (see pages 308-309).

Therefore, a person skilled in the art will not know how to practice the claimed method because the instant specification does not appear to provide sufficient enabling description and guidance regarding method of treating an immune disease by administering B-cell antibody or fragment thereof and/or B-cell antibody or fragment thereof that is conjugated to “therapeutic agent” and/or “a drug” and/or “a cytokine” without knowing the characteristics of antibodies, agents, drugs or cytokines.

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In conclusion, in view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

14. These are **New Grounds of Rejections**. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 78, 81-86, and 97-100 rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (US Patent 4,861,579) (see entire document).

Meyer et al. teach a method of treating immune diseases such as infection, autoimmune disease by administering an anti-B antibody or fragment thereof (see entire document, particularly columns 1-3). Meyer et al. further teach that said antibody can be conjugated with therapeutic agents such as radioisotopes, toxins, cytotoxic agents (e.g. see column 2).

Therefore, the reference teachings anticipate the claimed invention.

16. Claims 78, 79, 81, 93, and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Bussel et al. (Blood 1988 72;1:121-127) as evidenced by de Grandmont et al. (Blood 2003 101;8:3065-3073).

Bussel et al. teach method of treating immune thrombocytopenic purpura by administering intravenous immunoglobulins (IVIG) (see entire document, particularly Material and Methods on pages 121 and 124).

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As evidenced by de Grandmont et al, IVIGs are IgG solutions prepared from pooled plasma of healthy human donors and contain antibodies reacting against a large repertoire of antigens, including those on B lymphocytes (see entire document, particularly page 3065). Therefore, the reference method using IVIG would inherently encompass intact B-cell antibodies.

Further, although the reference is silent about B-cell antibody, it does not mean that the referenced IVIG does not bind epitopes on B-cell. Since the Office does not have a laboratory to test the referenced IVIG, it is applicant's burden to show that the referenced IVIG does not contain B-cell antibodies. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980). Furthermore, it does not appear that the claim limitation results in a manipulative difference in the methods steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d1508 (CAFC2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.

Therefore, the reference teachings anticipate the claimed invention.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 78, 80, 82-86, 95, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (US Patent 4,861,579) in view of Sivam et al. (US Patent 5,116,944).

The teachings of Meyer et al. have been discussed, supra, in Section 15.

The reference teachings differ from the claimed invention by not describing Fv, , single chain antibody, Fab, Fab', F(ab')₂, chimeric antibody, and antibody that is conjugated to cytokine.

However, the advantages of using Fv, Fab, Fab', F(ab')₂, chimeric antibody, and antibody that is conjugated to cytokine were well known in the art at the time the invention was made. For example, Sivam et al. teach antibody and its fragments such as Fv, single chain antibody, Fab, Fab', F(ab')₂, and chimeric antibody can be conjugated to cytokines to improve characteristic such as serum half-life of cytokines, stability, and receptor mediated uptake for better target delivery (see entire document, particularly columns 5-6). Further, Gowsala et al. teach said antibody conjugates can be used for enhanced therapeutic applications (see column 2, in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use antibody and its fragments conjugated to cytokines in a method of treating an immune disease because anti-B cell antibody can be used in methods of treating immune diseases and antibody and its fragments such as Fv, single chain antibody, Fab, Fab', F(ab')₂ can be conjugated to cytokines to improve characteristic for enhanced therapeutic effect.

Given the teachings of Meyer et al. regarding method of treating an immune disease using anti-B cell antibody, and the teachings of Sivam et al providing methods of making and using antibody and its fragment conjugated with cytokines, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of practicing the claimed method of treating an immune disease by using anti-B cell antibody and its fragments that are conjugated to cytokines.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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19. Claims 78, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (US Patent 4,861,579) in view of Fishwild et al. (Nature Biotech. 1996, 14:845-851).

The teachings of Meyer et al. have been discussed, supra, in Section 15.

The reference teachings differ from the claimed invention by not describing a human monoclonal antibody.

However, methods of making human monoclonal antibody and its use in therapy were well known in the art at the time the invention was made. For example, Fishwild et al. teach method of making human monoclonal antibodies using transgenic mice carrying human immunoglobulin gene loci; Fishwild et al. further teach that human monoclonal antibody is less immunogenic and have longer half-life in human, thus, more efficacious than murine antibody (see entire document, particularly page 845).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use human monoclonal anti-B cell antibody in a method of treating an immune disease because anti-B cell antibody can be used in methods of treating immune diseases and antibody and human monoclonal antibody is more efficacious in human.

Given the teachings of Meyer et al. regarding method of treating an immune disease using anti-B cell antibody, and the teachings of Fishwild et al. providing methods of making and using human monoclonal antibody, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of practicing the claimed method of treating an immune disease by using human monoclonal anti-B cell antibody.


Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder
Patent Examiner
July 16, 2007


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7/18/07